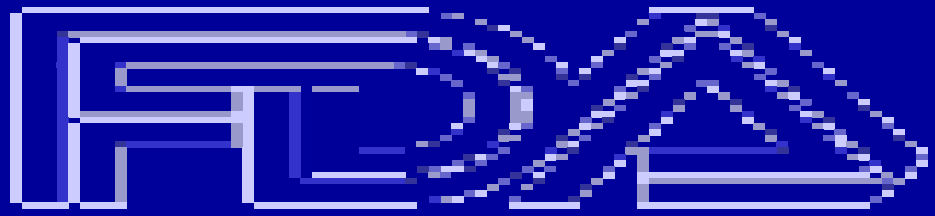


Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Establishments

RONDA LOYD-JONES,
INVESTIGATOR

DALLAS DISTRICT OFFICE

Feb. 1-3, 2005 – Dallas, Texas

UPON ARRIVAL

- CREDENTIALS AND IDENTIFICATION ARE SHOWN UPON ARRIVAL
- MOST RESPONSIBLE PERSON ONSITE IS REQUEST
- NATURE OF THE INSPECTION DISCUSSED
- FORM FDA 482, NOTICE OF INSPECTION IS ISSUED TO THE MOST RESPONSIBLE PERSON

FORM FDA 482

THIS FORM OUTLINES UNDER WHAT AUTHORITY THE INSPECTION IS BEING CONDUCTED UNDER

THINGS COVERED DURING THE INSPECTION

- ASK THE FIRM FOR AN OVERVIEW OF WHAT THE FIRMS DOES
- WHAT TYPES OF TISSUE DO YOU RECOVER/DISTRIBUTE/PROCESS
- GIVE A GENERAL FLOW OF YOUR OPERATION AND WHAT YOU DO
- TOUR THE INSPECTIONAL SITE

THINGS COVERED DURING THE INSPECTION CONT…

- COVERAGE AREA (HOW FAR DO YOU GO TO RECOVER, OR SHIP PRODUCT)

- DO YOU HAVE CONTRACTUAL AGREEMENTS WITH OTHER FIRM'S(WHO IS RESPONSIBLE FOR WHAT)

THINGS COVERED DURING THE INSPECTION CONT…

- WHO DO YOU PROVIDE YOUR HCT/P's TO(END USER EXAMPLE: DOCTORS, SURGEONS, BURN UNITS)

- DO YOU SHIP ONLY INTRASTATE OR DO YOU SHIP INTERSTATE OR INTERNATIONAL

THINGS COVERED DURING THE INSPECTION CONT…

- TOTAL NUMBER OF HCT/P's
  - DONORS
  - RECOVERED
  - TRANSPLANTED
  - DESTROYED
  - USED FOR RESEARCH

DOCUMENTS REVIEWED

- DONOR RECORDS
  - MEDICAL HISTORY
  - TEST RESULTS
  - RELEASE OF TISSUE
  - DISTRIBUTION

DOCUMENTS REVIEWED

- DOCUMENTS RELATED TO GOOD TISSUE PRACTICES(GTP's)
  - EXAMPLES:
    - SOP'S
    - COMPLIANTS
    - PRODUCT DEVIATIONS
    - PROCESS VALIDATION
    - TRACKING SYSTEM

DOCUMENTS RELATED TO GOOD TISSUE PRACTICES (GTP's)

- **THESE DOCUMENTS ARE REVIEWED TO ASSURE THE FIRM HAS ADDRESS THE CONCERNS ASSOCIATED CGTP's**

MEDICAL HISTORY

- REVIEW THE PROCESS FOR PERFORMING AND DOCUMENTING THE MEDICAL HISTORY OF THE DONOR
- REVIEW THE MEDICAL HISTORY QUESTIONNAIRE
- MAKE SURE THE QUESTIONS ARE WORDED TO ASSURE YOU WILL GET THE MOST ACCURATE AND CORRECT INFORMATION

MEDICAL HISTORY

- RECORDS ARE REVIEW FOR:
  - MISSING INFORMATION(BLANKS)
  - PROPER QUESTIONS
  - YES OR NO RESPONSES THAT SHOULD DISQUALIFY DONORS
  - DELETIONS/OMITTED INFORMATION

OBSERVATIONS

- ANY DEVIATION FROM PRACTICE OR PROCEDURE THAT GOES AGAINST GOOD TISSUE PRACTICES AND ASSOCIATED GOVERNING REGULATIONS THAT COULD POTENTIALLY AFFECT THE SAFETY OF THE HCT/P’s

- NON COMPLIANCE ISSUES

PURPOSE OF FORM FDA 483, INSPECTIONAL OBSERVATIONS

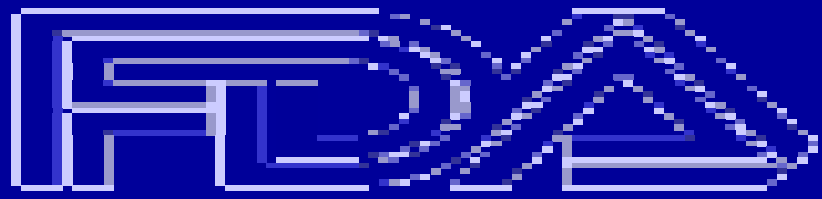
- DOCUMENTS AND ESTABLISHES WARNING TO THE FIRM
- ALLOWS VOLUNTARY CORRECTION TO OBSERVATION

IN CLOSING

OVERALL GOAL

TO ASSURE ALL ACTIVITIES RELATED TO GOOD TISSUE PRACTICES ARE:

- REVIEWED
- EVALUATED
- VERIFIED
- ARE IN COMPLIANCE



RONDA LOYD-JONES, INVESTIGATOR
DALLAS DISTRICT OFFICE
214-253-5242
RLOYD@ORA.FDA.GOV